REMARKS/ARGUMENTS

Claims 1-4 and 10-15 are pending in this application.

Support for the amendment to Claim 1 is found page 21, line 18 through 27 and page 14, lines 5-10.

No new matter is added.

The Examiner has rejected the claims as obvious in view of Bellini (US 6,251,876), or Mivoshi and Kawata (citing the PCT publications but using the U.S. Patents as the English equivalents).

The rejections are largely the same in that the Examiner argues that Bellini, US'267 and US'860 teach HA gels that are deemed to be the same as is in the claims. Each of these rejections also relies on Collins (US 6,096,728) to allege that it would have been obvious to include what Collins describes into the HA gels of the primary references of Bellini US'267 and US'860.

The Examiner has also rejected the claims in view of the claims of US'267, US'860, and two additional patents: US 6,638,538 and US 6,387,413.

Bellini requires additional substances to activate the HA, e.g., metal salts (see column 4). While Applicants understand that, during the prosecution of an application in the Office, claims are to be given their broadest reasonable interpretation consistent with the teaching in the specification (*In re Bond*, 710 F.2d 831, 833 (Fed. Cir. 1990)), it is error to disregard express limitations in the claims. The Examiner may not set up a "strawman" claim and reject it rather than subject matter encompassed by the actual claims.

The plain language of Applicants' claims requires no crosslinkers, Bellini includes them and the Examiner has put forth no reasoning based on evidence why the Bellini gels

would inherently be the same. It is, of course, the law of inherency that mere possibilities are not sufficient, what Bellini describes must result in that which is claimed.

Nonetheless, Applicants explain in the attached Rule 132 Declaration (currently unexecuted with signed copy to be filed shortly) why Bellini's material is different in terms of structure that results from how the present material is made (see amended claim 1 referencing Example 1 on page 21, which is reflected in amended claim 1) and how Bellini's material is made.

The hyaluronic acid gel of the present invention, prepared in the manner as set forth in Example 1 of the specification, differs from the cross-linked hyaluronic acid of U.S. Patent 5,676,964 and Bellini in that:

A) the hyaluronic acid gel of the present invention does not have lactonic bonds whereas Bellini's has lactonic bonds; and

B) the degree of esterification of the Applicants' hyaluronic acid gel is about 0.1%, whereas the degree of esterification of the cross-linked hyaluronic acid of U.S. Patent 5,676,964 and Bellini is from 1 to 60%, preferably 5 to 30% (column 2, lines 36-41 of U.S. 5,676,964).

Withdrawal of the rejection based on Bellini and Collins is requested.

To the rejections of Miyoshi or Kawata (cited under 35 USC 103(a) to the PCT publications and under the doctrine of obviousness-type double patenting to the U.S. patent counterparts) combined with Collins, Applicants cannot agree with the Examiner's conclusion. In the discussion below, Applicants reference the U.S. patent publications but the comments are equally applicable to the rejections citing the PCT publications.

US'267 describes HA gels without chemical cross-linkers or modifiers (see column 6, lines 15-18). In addition, it discusses acid hydrolysis (column 6) or making a salt of HA (see column 7 and the examples). US'860 discusses degradation by hydrolysis (column 7, lines 31-37) particularly using acid (column 8, lines 24-28 and the examples starting at column 10). It is, of course, acknowledged in all of the rejections that Miyoshi and Kawata do not describe Aa composition for treating bone infection, which comprises an antibiotic with a hyaluronic acid and/or a hyaluronic acid gel (see Claim 1) but that because Collins describes the combination of drug substances and cross-linked hyaluronan gels, it would have been obvious to put Collin's formulation into Miyoshi or Kawata's gels with a reasonable expectation of success (see, e.g. the Action at pages 4-5 for the Miyoshi PCT based rejection).

Applicants submit that unlike the disclosures of Miyoshi and Kawata, the HA gel of the present claims is intended to hold the antibiotic and releases the antibiotic by its biodegration (see for treating bone infection in claim 1 and page 15, line 27 to page 16, line 1 and lines 7-10). In contrast, the HA gels of Miyoshi and Kawata are transparent HA gels with fluidity, good biocompatibility and improved *in vivo* persistency are not designed to hold antibiotics and release antibiotics by their biodegradation. Collins's teaches an example of a material as a cross-linked gel of hyaluronan gel for a controlled release polymer meaning that the polymer must be able to relase the drug in a controlled manner. One of ordinary skill

in the art would not have been motivated to use the HA gel of Miyoshi and Kawata, designed not for retention, instead of the controlled release material required by Collins. Indeed, following the construct of the Examiner's rejection goes against the explicit requirements of the cited references, their requirements and purposes. It is, of course, not proper to ignore salient teachings that lead one away from a claimed invention.

Withdrawal of the rejections is requested.

To the rejections under the nonstatutory obviousness-type double patenting doctrine citing U.S. 6,638,538 and 6,387,413, Applicants file here a Terminal Disclaimer.

Applicants also request a Notice of Allowance for all pending claims.

Respectfully submitted,

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